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# ORDER FOR SUPPLIES OR SERVICES SCHEDULE - CONTINUATION

PAGE NO

2

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

 DATE OF ORDER
 CONTRACT NO.

 04/25/2017
 EP-W-17-006

**ORDER NO.** 0003

ITEM NO.	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT	AMOUNT	QUANTITY
(a)	(b)	ORDERED (c)	(d)	PRICE (e)	(f)	ACCEPTED (g)
(a)	SOW & Approved Cost Estimate	(0)	(u)	(e)	(1)	(9)
	COR: Nathan Mottl mottl.nathan@epa.gov					
	Alt. COR: Charles Bevington:					
	bevington.charles@epa.gov					
	bevingeon.endriebjepa.gov					
	Period Of Performance:					
	Bas Year: 4/25/17 through 4/24/18					
	Option Year One: 4/25/18 through 4/24/19					
	Incremental funding in the amount of					
	\$300,000.00 is hereby added, as a result					
	funds in the amount of \$347,631.57 are					
	required to fully fund the Base Period.					
	TOCOR: Nathan Mottl Max Expire Date:					
	04/24/2019					
	Admin Office:					
	HPOD					
	US Environmental Protection Agency					
	William Jefferson Clinton Building					
	1200 Pennsylvania Avenue, N. W.					
	Mail Code: 3803R					
	Washington DC 20460					
	Accounting Info:					
	16-17-B-69A-401CD6-2505-TPCAECZ-1669A16XX2-0	)				
	01 BFY: 16 EFY: 17 Fund: B Budget Org: 69A					
	Program (PRC): 401CD6 Budget (BOC): 2505					
	Cost: TPCAECZ DCN - Line ID: 1669A16XX2-001					
	Period of Performance: 04/25/2017 to					
	04/24/2019					
0001	Base Year: Task Order Type: T&M LOE HOURS				300,000.00	
	5,857.00 NTE \$647,631.57					
	Period Of Performance:					
	Base: 4/25/17 through 4/24/18					
	Fully Funded Obligation Amount: \$647,631.57					
	Delivery: 04/24/2018					
	Delivery Location Code: HPOD					
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	William Jefferson Clinton Building					
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# ORDER FOR SUPPLIES OR SERVICES SCHEDULE - CONTINUATION

EP-W-17-006

04/25/2017

PAGE NO

3

0003

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER CONTRACT NO. ORDER NO.

ITEM NO. SUPPLIES/SERVICES QUANTITY UNIT UNIT AMOUNT QUANTITY ORDERED PRICE ACCEPTED (d) (a) (e) (c) (g) Amount: \$647,631.57 0002 0.00 Year One: Task Order Type: T&M LOE HOURS Period Of Performance: Option Year One: 4/25/18 through 4/24/195,857 LOE Hours NTE: \$666,801.05 (Option Line Item) 04/24/2018 Delivery: 04/24/2019 Delivery Location Code: OIG SACO OIG SACO US Environmental Protection Agency William Jefferson Clinton West Building 1301 Constitution Ave., NW Rm. 2110; Mail Code 2450T Washington DC 20004 USA Amount: \$666,801.05 The obligated amount of award: \$300,000.00. The total for this award is shown in box 17(i). TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H)) \$0.00

#### RISK ASSESSMENT DIVISION (RAD)

#### **PROJECT TITLE:**

Existing Chemicals Programs: Preparation of Consumer, General Population, and Environmental Exposure Assessments (EP-W-17-006/Task Order 0003)

#### C. STATEMENT OF WORK (SOW)

#### C1. Background and Purpose

# Background

The Office of Pollution Prevention and Toxics (OPPT) of the Environmental Protection Agency (EPA) is responsible for work under a number of statutes including, principally, the Toxic Substances Control Act (TSCA), the Chemical Safety in the 21<sup>st</sup> Century Act, and Pollution Prevention Act of 1990 (PPA). The mission of the office is to assure that industrial chemicals are designed, manufactured, processed and used in ways that maximize their benefits to society and minimize their impacts on human health and the environment; encourage the replacement of older, more hazardous chemicals and technologies with new, safer alternatives; and work to harness the use of pollution prevention technologies, whenever feasible.

OPPT's Risk Assessment Division (RAD) is responsible for health and environmental hazard and risk evaluations of chemicals regulated under the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The Frank L. Lautenberg Chemicals Safety for the 21st Century Act amends the Toxic Substance Control Act (TSCA). Exposure Assessors within RAD develop the guidance for and/or produce exposure characterizations and assessments to support OPPT's risk evaluations. Exposures may be assessed for a variety of exposure scenarios, including but not limited to, ambient exposures for the general population, exposures to highly exposed individuals within the general population (e.g. subsistence fishers), consumer exposures within the indoor environment including highly exposed individuals (e.g. hobbyists), or exposures to ecological receptors.

Among other things, the new TSCA requires EPA to conduct risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation under the conditions of use. Furthermore, the new TSCA legislation requires that EPA adhere to specific provisions regarding Scientific Standards, Weight of Evidence and Availability of Information as articulated in Sections 26 (h), (i) and (j), respectively (<a href="https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act">https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act</a>). This SOW is supporting implementation of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, specifically for existing chemicals. The Contractor shall be familiar with the amended law to ensure that technical products abide to the scientific standards that EPA must meet when preparing technical products supporting OPPT's risk evaluations.

Under the amended TSCA, EPA is required to systematically prioritize and assess existing chemical substances and manage identified risks. Within six months from the date of the announcement that a chemical substance is subject to risk evaluation, EPA will issue a scoping document that will include information about the chemical substance, the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Agency expects to consider in the risk evaluation. TSCA generally requires that these chemical risk evaluations be completed within three years of initiation, allowing for a single 6-month extension.

The Contractor is expected to support the development of scoping documents, draft and final risk evaluations. Use dossiers will be developed to support the scoping and risk evaluation document, but the Contractor is not expected to work on this product. The use dossiers will include use information from literature sources and information obtained from outreach meetings with stakeholders. These will be compiled by another contractor with input from economists in the OPPT's Chemistry, Economics, and Sustainable Strategies Division and regulatory specialists in the Chemical Control Division and National Program Chemical Divisions.

Below is a short description of the contents of the scoping documents, draft and final risk evaluations, including, expected work for exposure.

- 1. Problem Formulation/Scoping<sup>1</sup>: During this stage, OPPT determines the exposure pathways, receptors and health endpoints that will be the focus of the risk evaluation for a particular substance or cluster under specific TSCA uses. Conceptual models, key assessment questions and the analysis plan document the conclusions of the problem formulation. Conceptual models are developed to capture the exposure pathways, receptor populations and effects that will be included in the human health and ecological risk evaluation. The key assessment questions are developed to drive the scope and analysis plan of the human health and ecological risk evaluation. Note, that not all data sources need to be reviewed in detail for purposes of the scoping documents. Scoping documents are required within 6 months of announcement of high-priority chemicals.
- 2. Draft Risk Evaluation and public comment: This step involves developing a risk evaluation document containing the technical contributions of multiple disciplines. The description here is specific to exposure assessment. All monitoring studies should be reviewed, relevant information extracted, and media-specific information incorporated into reporting tables. All modeling scenarios should be defined, estimated or measured model inputs defined, model choice documented, and model outputs (deterministic or probabilistic) documented. The combination of monitored and/or modeled estimates of media-specific concentration and dose should be aggregated, as appropriate, for defined receptor groups including potentially exposed and susceptible subpopulations, to the extent data are available.
- 3. Final Risk Evaluation: Should additional information become available through public comment, literature review, required testing, or other sources, EPA will update its draft risk evaluation to refine existing exposure scenarios, develop new scenarios, or combine scenarios for purposes of aggregate exposures for receptor groups in different ways.

OPPT uses "fit-for-purpose" systematic reviews where the scope and purpose of the scientific analysis for collecting, evaluating and integrating the data supporting our decisions are defined during problem formulation. This framework is consistent with the general framework for conducting exposure assessments with excerpts from the 2013 Standing Operating Procedures (SOPs) included in the supplemental document, *Background Information for QAPP Development*<sup>2</sup>. The fit-for-purpose systematic reviews generally follow an iterative process when new data become available. Iterations may also happen at any given step of the systematic review process. The Contractor shall use the procedures outlined in the supplemental document for data collection and data evaluation of exposure information. Also, the contractor shall follow, as applicable, EPA guidance documents cited in the supplemental document when providing technical support for exposure-related work under this SOW. Below is a brief

<sup>&</sup>lt;sup>1</sup> The amended TSCA uses the term "scoping document" which is equivalent to problem formulation. Examples of problem formulation documents can be found at <a href="https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals#formulation">https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals#formulation</a>

<sup>&</sup>lt;sup>2</sup> EPA. 2013. Standard Operating Procedures for the Exposure Assessment Branch's Exposure Assessment of Chemicals.

description of the steps in the systematic review process being used in our scoping documents, draft assessments and final assessments. The overview below and Section C.3 will provide information on what steps the contactors will and will not be involved with.

- 1. *Data Collection*: OPPT intends to collect most of the data/information upfront to support the scoping/problem formulations and chemical risk evaluations. Data will be collected under a defined set of literature search criteria and data sources for the different disciplines supporting the risk evaluation (chemistry, fate, engineering, exposure, human health hazard toxicology, ecotoxicology). The HERO database<sup>3</sup> will be used as an overall repository for all identified data sources. HERO access will be provided to the Contractor. However, another contractor will take the lead for conducting the majority of the data collection activities.
- 2. *Data Evaluation:* In the *Data Evaluation* phase, the collected data/information are critically appraised to determine their quality and utility. It can be subdivided in further steps.
  - a. Screening of literature to identify data/information that are potentially suitable and useful in the scoping document and risk evaluation. Review includes title review and abstract review. Search strategies and review criteria (inclusion/exclusion) will need to be documented, including using of tagging tools within HERO. Another contractor will be performing these steps.
  - b. Extraction, tabulation and development of study summaries which will assist in the evaluation of the reliability and relevance of studies. The Contractor may be asked to help with this step.
  - c. Evaluation of the reliability and relevance of studies to determine whether the information is of appropriate quality to be used in the assessment. For purposes of developing conceptual model and analysis plan in the scoping documents, chemical-specific, use-specific (from use dossiers), and discipline-specific data sources (from *Data Collection* step) will be analyzed at a high-level to inform development of exposure scenarios that will be assessed for risk assessment. This may include full-text review for a subset of the identified data sources. The Contractor may be asked to help with this step.
- 3. *Data Integration:* This is the step where all of the relevant data are combined and analyzed. OPPT uses a weight of evidence (WOE) approach when evaluating and synthesizing multiple evidence streams to support chemical risk evaluations. The Contractor may be asked to help with this step.
- 4. Summary of Findings and Identification of Data Gaps: OPPT will take risk management actions when unreasonable risks are identified throughout the risk evaluation process. Thus, it is critical that the findings of the systematic review are summarized in plain language, and any uncertainties and areas for further research are identified. The Contractor may be asked to help with this step.

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<sup>&</sup>lt;sup>3</sup> Health and Environmental Research Online (HERO), https://hero.epa.gov/hero/

The primary purpose of this SOW is to provide technical support related to consumer, general population, and environmental exposure assessments<sup>4</sup> and characterizations<sup>5</sup> and other exposure-related activities<sup>6</sup> pertinent to existing chemical substances.

Most of the work for this task order will be towards developing and supporting exposure characterizations and assessments for risk evaluation for the 10 chemicals listed in Table 1. The scoping document is the first step of the risk evaluation process of these chemicals, as announced in the December 19, 2016 Federal Register (FR) notice<sup>7</sup>, and is due within six months from the date of the publication of the FR notice (i.e., June 19, 2017). The Contractor will initially support the development of the scoping documents and then move to work supporting the analysis phase of the risk evaluation. However, additional work beyond this list of 10 chemicals is anticipated.

The Contractor will develop various technical products to support these activities such as, but not limited to, exposure assessments, exposure characterizations, briefing presentations, white papers, response to comments, generation of exposure model inputs and outputs, model maintenance, development, or refinement, database development, Quality Assurance and/or Quality Control project plans and/or of work products, supplemental fit for purpose literature searches and Endnote libraries, monitoring data identification and summarization, and related tasks that will be clarified as indicated in the statement of work.

This SOW does not cover exposure support activities for risk management activities such as regulations. These activities will be covered in a separate SOW.

**Chemical Name** Relative amount of work completed to date under TSCA Work Plan **Chemical Program** Trichloroethylene Final Risk Assessment complete for targeted uses. Additional uses, exposure (TCE) pathways, and receptors need to be considered. Final Risk Assessment complete for targeted uses. Additional uses, exposure Methylene chloride pathways, and receptors need to be considered. Final Risk Assessment complete for targeted uses. Additional uses, exposure N-Methylpyrrolidone pathways, and receptors need to be considered. (NMP) 1,4-Dioxane Problem Formulation document complete and draft assessment is underway. Additional uses, exposure pathways, and receptors need to be considered. Cyclic Aliphatic Problem Formulation document complete and draft assessment is underway. Bromide Cluster Additional uses, exposure pathways, and receptors need to be considered. (HBCD) 1-Bromopropane Draft Risk Assessment is complete for targeted uses. Additional uses, exposure pathways, and receptors need to be considered.

Table 1: List of Initial 10 Chemicals for Risk Evaluation under TSCA

<sup>&</sup>lt;sup>4</sup> Exposure assessments are documented and quantified estimates of exposure that require more effort than exposure characterizations.

<sup>&</sup>lt;sup>5</sup> Exposure characterizations may be qualitative or quantitative in nature and are usually completed before an exposure assessment.

<sup>&</sup>lt;sup>6</sup> Exposure support activities are discrete tasks that support an exposure assessment or exposure characterization but are not specific to a given chemical substance.

<sup>&</sup>lt;sup>7</sup> Federal Register notice announcing the first 10 chemicals for risk evaluation: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0718-0001

Pigment Violet 29	Problem Formulation document is underway. Additional uses, exposure
(Anthra[2,1,9-	pathways, and receptors need to be considered.
def:6,5,10-	
d'e'f']diisoquinoline-	
1,3,8,10(2H,9H)-	
tetrone)	
Carbon Tetrachloride	Prioritization only. All uses, exposure pathways, and receptors need to be
	considered in development of scoping document.
Tetrachloroethylene	Prioritization only. All uses, exposure pathways, and receptors need to be
(also known as	considered in development of scoping document.
perchloroethylene)	
Asbestos	Prioritization only. All uses, exposure pathways, and receptors need to be
	considered in development of scoping document.

#### C.2 Scope of Work

The purpose of this procurement is to provide time and materials support for exposure assessment of existing chemicals for OPPT. This is not a firm fixed price statement of work.

The contractor shall supply the necessary resources required for the performance of this contract. The scientific quality of reviews, assessments, reports, model tools, statistical programs and software, and their timely preparation in accordance with negotiated schedules, are of paramount importance in the performance of this contract.

The contractor shall have the necessary technical and scientific expertise, knowledge and experience to successfully perform all of the tasks identified below. In addition, the contractor shall have a quality assurance/quality control program that maintains the quality of products, as well as an ongoing training program. This is intended to ensure that the contract staff produces quality products, and feedback from OPPT on needed improvements is communicated to the contractor's staff. The contractor shall maintain and make available upon request complete documentation of QA/QC practices and procedures. Performance of work under this contract shall be initiated by competitive task orders issued by the Contracting Officer, and will encompass tasks in following areas discussed below in Section III (TASKS).

#### C.3 TASKS

#### TASK 1: Project Management

The Contractor shall provide a Project Manager. The Contractor Project Manager shall report on all aspects of the objectives and progress of this contract to the designated EPA Contracting Officer (CO) and Contracting Officer Representative (COR) via email, through monthly reports. The Contractor Project Manager also plans, conducts and supervises Task Order (TO) projects, necessitating advanced knowledge and the ability to originate and apply new and unique methods and procedures. The Contractor Project Manager provides advice and counsel to other professionals. The Contractor Project Manager shall notify via email the relevant EPA COR/Alternate COR or TO COR of any significant difficulties in accomplishing the task listed in the TOs.

In cases where performance objectives and minimum Acceptable Quality Levels (AQLs) are not being met, the Contractor Project Manager will make every effort to immediately correct the problems to ensure customer satisfaction. If the problem persists, the Project Manager will submit a plan of corrective action

to the TO COR and the Contract Level COR. The Contractor Project Manager shall ensure that the approved Quality Assurance (QA)/Quality Control (QC) process is followed to ensure the quality of its products.

The contractor shall schedule a kick-off call with the EPA to review overall goals of the project and details regarding implementation of the TO. Roles and responsibilities for completing the tasks below will be discussed. The kick-off call shall be scheduled within 3 working days of award at a mutually agreed upon time. During the kick-off call the contractor and EPA will schedule monthly technical calls.

#### **TASK 2: Reporting Requirements**

The contractor shall write and submit monthly progress reports to the EPA Contracting Officer Representative (COR). Progress reports shall describe completed work during the invoice period and should link to charges described in invoice documentation.

Routine progress reports shall include a written monthly technical progress report that includes the following in the case of each project that the contractor is involved in during the month: (a) an overview of work accomplished since project inception to to-date (b) a description of work accomplished during the month, (c) a summary of QA/QC activities since project inception including a summary of corrective action taken (d) a brief summary of anticipated work during the following month, (e) a summary and details of the LOE and costs incurred **for each task** during the month and cumulatively , and (f) total remaining LOE and budget. This report shall also be issued to the Contract Level COR. Routine progress reports shall be delivered electronically; paper copies are not needed.

The Contractor shall notify the TOCOR and CO when 75, 90, and 100% of approved hours have been expended. No work on the conduct of environmental data operations can begin until EPA approval of the QAPP is obtained. Work not related to environmental data operations such as scoping how environmental data may be searched for or summarized once available including refinement of keywords, criteria, or report templates may begin prior to QAPP approval. See Appendix K for additional invoice reporting instructions.

Failure to submit monthly progress reports with the information required will result in the suspension of the invoice until such supporting documentation is provided. Any deviations from the project such as work schedules, impediments encountered, and budget require approval from the EPA COR. The EPA COR may also initiate verbal communications with the contractor on an as needed basis to determine project status.

<u>Deliverable</u>: Monthly Progress Reports shall be submitted to the EPA COR within three (3) calendar days of invoice submission to EPA. Minimal level of effort required for this deliverable.

# **TASK 3: QAPP Requirements**

Quality Assurance: The Quality Management Plan, the QAPP for Tasks 4 through 7. The contractor shall adhere to its Quality Management Plan that is tailored for this contract.

This Task Order involves the use of existing data. Accordingly, EPA policy requires that an approved Quality Assurance Project Plan (QAPP) be in place before any work begins that involves the collection, generation, evaluation, analysis or use of environmental data. The QAPP must be consistent with EPA Requirements for Quality Assurance Project Plans: EPA QA/R-5 (https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf).

- \* Within 10 business days after Task Order Award, the contractor shall prepare and submit for EPA review a draft Quality Assurance Project Plan (QAPP) for Tasks 4 through 7.
- \* EPA will review the contractor's draft QAPP, and provide the Contractor with written approval or written comments.
- \* If needed, the Contractor shall submit a revised QAPP within 5 business days of receipt of the written comments on the draft QAPP, unless otherwise instructed by the EPA TOCOR.
- \* Under no circumstances shall work that involves the generation, collection, evaluation, analysis, or use of environmental data be performed by the contractor until the contractor receives written notification from the EPA TOCOR that EPA has approved the contractor's QAPP.

All QA documentation, including the QAPP, prepared under this TO, shall be considered non-proprietary, and shall be made available to the public upon request.

# Additional QA Documentation Required

In addition to the requirements described above, all major deliverables (e.g., Technical Support Documents, Study Reports, Study Plans, etc.) produced by the Contractor under this Task Order must include a discussion of the QA/QC activities that were or will be performed to support the deliverable. The contractor shall immediately notify the EPA TOCOR of any QA problems encountered that may impact the performance of this Task Order, with recommendations for corrective action.

The contractor also shall provide EPA with monthly reports of QA-related activities performed during implementation of this Task Order. These monthly QA reports shall identify QA activities performed to support implementation of this task order, problems encountered, deviations from the QAPP, and corrective actions taken. The contractor may include this as a part of the contract-required monthly financial/technical progress report. The contractor shall notify the EPA TOCOR at any time during the task order if changes to the QAPP are warranted (e.g., due to organizational changes, revised technical approaches).

If, during the Period of Performance of this Task Order, the EPA TOCOR determines revisions to the QAPP are necessary, the contractor shall submit a revised QAPP, including the revision summary, within 5 business days after receiving written technical direction to do so. EPA will review the draft revised QAPP and provide the contractor with written approval or comments. The contractor shall provide a revised QAPP, then a final QAPP that responds to EPA's written comments within 5 business days of receipt of EPA's comments on the draft QAPP.

\* Under no circumstances shall work involving environmental data be performed by the contractor until the contractor receives written notification from the EPA TOCOR that EPA has approved the contractor's QAPP.

Since this task order involves the collection, evaluation, and use of environmental data by and for the Agency, the contractor shall implement a quality system that meets ANSI standard E4-2014 and prepare a quality assurance project plan (QAPP) following EPA guidelines. QAPP is due within 15 days of task order award.

# Task 4: Identification and Evaluation of Data Sources used for Scoping Documents

The contractor shall document the approach taken to search for data sources used to support the development of scoping documents and risk evaluations for those chemicals listed in Table 1. The data sources will be used to develop a conceptual model and analysis plan, which document the conclusions of the scoping/problem formulation of each chemical listed in Table 1. Note that another contractor will be conducting the majority of literature searches. Fit for purpose supplemental literature searching may be initiated through technical direction to provide answers to specific questions.

EPA may identify additional candidate chemicals or categories during the course of the performance year of the task order, in addition to those listed in Table 1.

#### Subtask 4.1. Data Collection

In general, EPA anticipates that this task order will support targeted fit-for-purpose data gathering activities intended to provide answers to specific questions. In that case, the contractor shall perform data gathering activities according to the strategy outlined in *Attachment: Background Information for QAPP Development*. Before starting literature search, the Contractor shall develop a literature search and screening protocol, in collaboration with the EPA TOCOR and EPA technical contacts, to describe the process(es) used to identify, screen and categorize references. The literature search strategy shall include search terms geared to gather information on susceptible populations since the amended TSCA requires to incorporate susceptible populations in their risk evaluations. When performing the literature searches, the contractor shall communicate with the EPA TOCOR and technical contacts regularly to ensure that searches are refined and focused.

The contractor shall document the literature search strategy and findings in a document that will be provided to EPA as a deliverable. This document should include, as a minimum, the following:

- keywords used and databases searched
- number of references screened and selected, including criteria-based rationale for including and excluding records. Note review of title and abstract may be sufficient to screen some data sources, while full-text review may be needed for other data sources.
- PRISMA flow diagram that graphically illustrates the number of titles, abstracts, and full articles reviewed during the literature search process.

Contractor shall prepare a reference library in EndNote and submit to EPA as deliverable. Contractor shall perform a QA/QC of all data delivered to EPA for incorporation into the exposure characterizations supporting the scoping documents.

*Deliverables*- End note file is due within 3 weeks of receipt of technical direction from TOCOR. Depending on the number of data sources identified and the number of concurrent searches this timeframe may extended no more than 2 weeks based on feedback from EPA TOCOR.

#### Subtask 4.2. First Tier Data Evaluation and Synthesis

Data sources evaluated for use in scoping documents will need to be summarized. Some amount of categorization, review, qualitative, semi-quantitative, or quantitative extraction of data will be required to incorporate these citations into the scoping documents. The TOCOR will follow-up with chemical-specific technical direction to ensure that the level of data evaluation is sufficient (no more and no less) to enable development of conceptual model and analysis plan for the scoping documents (see Task 5). The contractor shall document the screening process for evaluating relevancy and quality of the literature based on criteria outlined in Background Document for Developing QAPP and provide report to EPA as part of QAPP.

*Deliverables*- EndNote file and accompanying report (Microsoft Word or Excel) documenting criteria and screen to identify data sources used is due within 3 weeks of receipt of technical direction from TOCOR.

Depending on the number of data sources identified and the number of concurrent searches this timeframe may extended no more than 2 weeks based on feedback from EPA TOCOR.

Collection of available literature and data sources through systematic review should be undertaken with targeted evaluation and thorough and complete QA/QC of all data delivered to EPA for incorporation into exposure characterization. The contractor shall assume between 3 and 5 exposure characterizations will be ongoing within any given month.

Individual interim products shall be delivered to the TOCOR within 2 weeks of receipt of written technical direction from the TOCOR, and final exposure assessments shall be delivered to the TOCOR within 1 week after comments received on interim assessments from EPA.

#### Task 5: Develop Exposure Characterizations for Scoping Documents

The contractor shall develop exposure characterizations candidate chemicals or categories identified by EPA (see Table 1, although additional chemicals may be identified over time). These assessments will provide a qualitative, semi-quantitative, or quantitative assessment of available data sources identified under task 4 to support an exposure characterization including available monitoring data, modeling approaches, and likely exposure pathways and media relevant for human or ecological exposure, depending on the chemical substance of interest. If data evaluation beyond first-tier is done for targeted sources, the contractor must document the process, as this will be part of the systematic review that will be integrated into HERO.

As described in Task 4, identification and evaluation of available data sources through systematic review should be completed with QA/QC for all data delivered to EPA for incorporation into exposure characterization. Exposure characterizations may include narratives or graphics that support development of conceptual models, description of analysis plan, or overall approaches to complete an exposure assessment.

The contractor shall assume between 3 and 5 exposure characterizations will be ongoing within any given month. Individual interim products shall be delivered to the TOCOR within 2 weeks of receipt of written technical direction from the TOCOR, and final exposure characterizations shall be delivered to the TOCOR within 1 week after comments received on interim assessments from EPA.

# Task 6: Development of Components of Exposure Assessments for TSCA Risk Evaluations

#### **Subtask 6.1 Exposure Assessment Support**

The contractor shall develop components of exposure assessments for chemicals or categories identified by EPA. These assessments are initiated and completed following the completion of a scoping document. The assessments will incorporate and interpret information on chemistry, fate, uses, and releases as produced by other disciplines. Exposure assessments will include a description of exposure scenarios, receptors, media concentrations and associated doses (if needed) for all identified uses across the lifecycle of the chemical. Aggregate exposures for all conditions of use for receptor groups including potentially exposed and susceptible subpopulations are now required.

These assessments include updates to the literature search described in Task 4, monitoring data compilation and summarization, derivation of model inputs and outputs, characterization of receptor groups and how they are differently exposed, uncertainty and sensitivity analysis. The contractor shall extract, tabulate, and develop summarizes that assist in the evaluation of the reliability and relevance of studies. The contractor shall collect, evaluate, integrate, and summarize of data sources identified through

systematic review with QA/QC of all data delivered to EPA for incorporation into the risk evaluation documents should undergo thorough QA/QC.

The contractor shall assume that between 3 and 5 components of exposure assessments will be ongoing within any given month. Individual interim products shall be delivered to the TOCOR within 2 months of receipt of written technical direction from the TOCOR, and final exposure assessments shall be delivered to the TOCOR within 1 month after comments received on interim assessments from EPA. The contractor shall assume that between one-third and two-thirds all components of a chemical-specific exposure assessment will be completed within the 12-month period of performance given the overall timeline for project completion (3 years).

#### Subtask 6.2. Data Collection

There may be circumstances that a limited literature search may be needed due to new literature published since the cut-off date for the literature search done as part of subtask 4.2, or information received from the public during the public comment period. In that case, the contractor shall consult with the EPA TOCOR on the nature and extent of the data gathering activities supporting the risk assessment. Supplemental literature searches will be conducted according to the strategy outlined in the *Attachment: Background Information for QAPP Development* as specified in Subtask 4.1. The contractor shall update the report documenting the literature search strategy and findings and EndNote library to reflect new literature identified and considered for the exposure assessment.

*Deliverables* - Updated EndNote library shall be delivered to the TOCOR within 3 weeks of receipt of technical direction from EPA TOCOR.

#### Subtask 6.3. Data Evaluation and Synthesis

The Contractor will build on the data evaluation and synthesis conducted during subtask 4.2. Since EPA must be transparent on the data considered and used for the risk assessment, the Contractor shall extract information from identified literature using a template table provided by EPA. The Contractor may modify template table in consultation with the EPA TOCOR. The Contractor will extract information into template table and provide it to EPA as deliverable. The Contractor shall perform a quality assurance check for the data tables prior to delivering them to EPA. Quality assurance checks shall include, but not limited to comparing table entries to information from the original publication and checking conversions as appropriate (e.g., ppm to mg/m³). The quality assurance check should be performed by a scientist that was not involved in the initial development of the table being reviewed. The contractor shall update the report documenting the screening process for evaluating relevancy and quality when new literature is considered for the risk assessment. The relevancy and data quality screening process will follow the criteria outlined in the *Attachment: Background Information for QAPP Development* and provide report to EPA as deliverable.

*Deliverables*- Updated list of data sources identified for inclusion in assessment shall be delivered to the TOCOR within 3 weeks of receipt of technical direction from EPA TOCOR.

#### **Task 7: Exposure Support Activities**

The Contractor shall use guidelines developed in the QAPP and available data sources provided by EPA to develop exposure assessment support materials for the scoping and risk assessments listed in Table 1. Exposure support materials include derivation of approaches to quantify exposures that are not specific to a chemical substance such as the following examples. Specific activities under this task will be determined through technical direction. The contractor shall assume that between 5 and 10 exposure assessment support activities will be needed during the period of performance.

Interim products may be acceptable for some exposure support activities as the finalization will occur through follow-up task orders. Final products will be required for others. This will be determined through technical direction.

Examples of such activities are listed below.

- Derivation of exposure factors and activity patterns specific to a given age group or sub-group within the general population.
- Developing or refining a modeling approach for an overall group of chemicals such as differentiating between vapors and particles with air modeling estimates.
- Consideration of read-across use of analog monitoring data for a given media and chemical category to determine distribution of chemical substance
- Within an exposure scenario, consideration of central tendency, high-end, and bounding estimates and estimation of distribution of exposure given relatively poor data availability and relatively richer data availability.
- Updates to data sources and databases used to support exposure modeling. Examples include developing summary statistics for flow data of REACH (rivers) within the contiguous United States, databases on chemicals in product use and product use patterns, or updates to measured emission rates, mass-transfer rates, or partition coefficients that inform emission and fate and transport of chemicals in indoor and outdoor environments.
- Developing scaling factors to determine whether existing model outputs can be adjusted based on consideration of either new source or new receptor information to approximate refined model outputs.

**Deliverables for task 7:** Individual interim products shall be delivered to the TOCOR within 2-3 weeks of receipt of written technical direction from the TOCOR, and final exposure support activities shall be delivered to the TOCOR within 1 week after comments received from EPA.

#### C.4 Reporting Requirements and Deliverables

As described in Task 2 and in the invoice instructions, the Contractor shall provide a monthly report CO, COR and TOCOR which identifies project staff and all activities and milestones associated with the Task Order assignments planned and in progress. The monthly report in progress tasks shall be included in the monthly reports which will be referenced when the Voucher Validation review is performed monthly at the end of each billing cycle.

As per the Task Order or request for a proposal, the Contractor shall provide the Agency with a proposal within the timeframe specified for this Task Order. The EPA CO, CORs, or panel members will review the proposal and provide the Contractor with an approval or disapproval, and revision (if necessary) in writing. The timelines involved, will proceed as stipulated in the request for a proposal or Contract

The Contractor shall prepare a Quality Assurance Project Plan for this Task Order. <u>EPA Requirements for Quality Assurance Project Plans (QA/R-5).</u>

For most deliverables, the EPA COR will assign a tentative due dates and instructions when work is routed to the Contractor. If within three business days, the Contractor expresses no concern regarding the due date; the date shall be deemed settled by tacit agreement.

# SPECIFIC SCHEDULE OF DELIVERABLES:

Tasks	Deliverables	Schedule
Task 1	Project Management	None
Task 2	Monthly progress reports	Monthly reports
Task 3:	QAPP and monthly progress reports	QAPP: Within 10 business days after award of task order
Task 4:	Systematic Review: Identification and Evaluation of Data Sources used for TSCA Work Plan Scoping Documents	<ul> <li>4.1 Final products shall be submitted within 3 weeks of receipt of technical direction from TOCOR. Depending on the number of data sources identified and the number of concurrent searches this timeframe may extended no more than 2 weeks based on feedback from EPA TOCOR.</li> <li>4.2. Final products shall be submitted within 3 weeks of receipt of technical direction from TOCOR. Depending on the number of data sources identified and the number of concurrent searches this timeframe may extended no more than 2 weeks based on feedback from EPA TOCOR.</li> </ul>
Task 5:	Exposure Characterizations	Within 2 weeks for draft, within 1 week for final.
Task 6:	Exposure Assessments	<ul> <li>6.1 Within 2 months for draft, within 1 month for final.</li> <li>6.2 Within 3 weeks of receipt of technical direction from EPA TOCOR.</li> <li>6.3 Within 3 weeks of receipt of technical direction from EPA TOCOR.</li> </ul>
Task 7:	Exposure Support Activities	Within 2-3 weeks for draft, within 1 week for final.

# **C.5 Acceptable Quality Level for Tasks**

See Attachment: Quality Assurance Surveillance Plan

Performance Criteria Analysis – TASKS						
Performance Indicator	Standard	Acceptable Quality Level (AQL)				
Timely submission of report	Reports submitted within time frame pre-negotiated with Task Order COR	95%				

Free of substantive technical, guideline, or format errors	Reports submitted with zero substantive errors including but not limited to discrepancies, omissions, inaccuracies, and/or inappropriate data evaluation	95%
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#### C.6 Method of surveillance

Final deliverables prepared by the contractor undergo a secondary review process in OPPT. Each report has a designated EPA reviewer. The EPA reviewer conducts a review of the contractor's deliverable. The EPA reviewer will provide feedback to the TOCOR to send back to the contractor should revisions be needed. The TOCORs will compare agency due dates or approved revised due dates to completed date of reports, quarterly and calculate the percentage of late reports. See attachment J.5 of this RFTOP.

#### C.7 Period of Performance

The period of performance of this task order is: 12 months from date of award with option to extend see (G.1 FAR 52.217-9 Option to Extend the Term of the Contract)

Base: 4/25/17 through 4/24/18

Option to Extend Year One: 4/25/18 through 4/24/19

C.8 Task Order Type

Time and Materials

# D. INSPECTION AND ACCEPTANCE

#### **D.1 Quality Assurance Project Plan**

The contractor shall submit the following quality system documentation to the CO at the time frames identified below:

	Documentation	Specifications	Due
X	Quality Assurance Project Plan for the Task Order	EPA Requirements for Quality	Task Order
		Assurance Project Plans (QA/R-	proposal
		5) [dated 03/20/11]	due date

This documentation can be found on the following EPA website – <a href="https://www.epa.gov/quality/epa-qar-5-epa-requirements-quality-assurance-project-plans">https://www.epa.gov/quality/epa-qar-5-epa-requirements-quality-assurance-project-plans</a>

This documentation will be prepared in accordance with the specifications identified above or equivalent specifications defined by EPA.

The Government will review and return the quality documentation, with comments, and indicating approval or disapproval. If necessary, the contractor shall revise the documentation to address all comments and shall submit the revised documentation to the government for approval.

The contractor shall not commence work involving environmental data generation or use until the Government has approved the quality documentation.

#### E. TASK ORDER ADMINISTRATION DATA

#### **G.1 Contract Administration Representatives**

Contracting Officer & Contract Specialist: Jessica Wilson, Wilson, Jessica@epa.gov

Task Order Contracting Officer's Representative: Nathan Mottl, mottl.nathan@epa.gov

Alt. Task Order Contracting Officer's Representative: Charles Bevington, Bevington.charles@epa.gov

# F: Invoicing

Invoices shall be submitted electronically to: US EPA FINANCE OFFICE AT <u>DDC-KINVOICES@EPA.GOV.</u> Copy the CO, Contract COR and TOCOR on the submission.

For format and guidance refer to: <a href="http://www2.epa.gov/financial/contracts#Contract\_invoices">http://www2.epa.gov/financial/contracts#Contract\_invoices</a>
The customer service contact information for the finance office is <a href="mailto:contractpaymentinfo@epa.gov">contractpaymentinfo@epa.gov</a> and 919-541-1148.

### G. TASK ORDER CLAUSES

#### G.1 FAR 52.217-9 Option to Extend the Term of the Contract (Mar 2000)

- (a) The Government may extend the term of this contract by written notice to the contractor within 5 calendar days before the expiration of this contract; provided that the Government gives the contractor a preliminary written notice of its intent to extend at least 30 days before the contract expires. The preliminary notice does not commit the Government to an extension.
- (b) If the Government exercises this option, the extended contract shall be considered to include this option clause.
- (c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 24 months.

(End of clause)

#### G.2 EPAAR 1552.237-72 Key personnel. (APR 1984)

(a) The contractor shall assign to this contract the following key personnel:

#### 1. Project Manager:

The contractor shall identify a Project Manager to serve as USEPA's primary point-of-contact and to provide supervision and guidance for all contractor personnel assigned to the task order. The Project Manager is ultimately responsible for the quality and efficiency of the support effort, to include both

technical issues and business processes. The Project Manager shall have knowledge in the technical areas described in the Task Order. The Project Manager shall assign tasks to contractor personnel, supervise ongoing technical efforts, and manage overall task order performance. The Project Manager plans, conducts and supervises projects of major significance, necessitating advanced knowledge and the ability to originate and apply new and unique methods and procedures. Schedules work to meet completion deadlines. The Project Manager shall possess demonstrated excellent written and oral communications skills.

The Project Manager shall have experience in managing projects of similar size and scope as demonstrated by appropriate combination of education and experience.

### 2. Quality Assurance Manager

The Quality Assurance (QA) Manager must have experience in exposure assessment with the ability to critically evaluate the type of data described in the task order. The QA Manager shall have advanced knowledge and the ability to originate and apply new and unique methods and procedures. Provide technical advice and counsel to other professionals with special emphasis on procedures for execution of systematic review. Generally, operates with a wide latitude for non-reviewed actions or decisions. Schedules work to meet completion deadlines. Directs assistance, reviews progress and evaluates results; makes change in methods where necessary.

The QA Manager shall have experience in quality management, implementation of quality management plan, and ensuring quality of projects of similar size and scope as demonstrated by appropriate combination of education and experience.

# H: TSCA SCOPING DOCUMENT and RISK ASSESSMENT EXAMPLES (TEMPLATES)

Caveats: These are examples rather than templates. Scoping documents were previously called "problem formulation and initial assessment" documents. The conceptual model and the analysis plan are the main products of the scoping process. The risk assessments completed to date have covered targeted uses. Risk assessments under the new TSCA will require assessment of aggregate exposures to all exposed population groups including potentially exposed and susceptible subpopulations for all conditions of use, to the extent data are available to do so.

More information can be found at <a href="https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals">https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals</a>

### **I: INVOICE PREPARATION INSTRUCTIONS: SF 1035**

The information which a contractor is required to submit in its Standard Form 1035 is set forth as follows:

- (1) U.S. Department, Bureau, or Establishment insert the name and address of the servicing finance office.
- (2) Voucher Number insert the voucher number as shown on the Standard Form 1034.
- (3) Schedule Number leave blank.
- (4) Sheet Number insert the sheet number if more than one sheet is used in numerical sequence. Use as many sheets as necessary to show the information required.

- (5) Number and Date of Order insert payee's name and address as in the Standard Form 1034.
- (6) Articles or Services insert the contract number as in the Standard Form 1034.
- (7) Amount insert the latest estimated cost, fee (fixed, base, or award, as applicable), total contract value, and amount and type of fee payable (as applicable).
- (8) A summary of claimed current and cumulative costs and fee by major cost element. Include the rate(s) at which indirect costs are claimed and indicate the base of each by identifying the line of costs to which each is applied. The rates invoiced should be as specified in the contract or by a rate agreement negotiated by EPA's Cost Policy and Rate Negotiation Branch.
- (9) The fee shall be determined in accordance with instructions appearing in the contract.

NOTE: Amounts claimed on vouchers must be based on records maintained by the contractor to show by major cost element the amounts claimed for reimbursement for each applicable contract. The records must be maintained based on the contractor's fiscal year and should include reconciliations of any differences between the costs incurred per books and amounts claimed for reimbursement. A memorandum record reconciling the total indirect cost(s) claimed should also be maintained.